



Application No. 10/736,489
Reply to Examiner's Answer of May 4, 2007
Paper Dated July 5, 2007
Attorney Docket No. 4133-031323 (P-6125)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application No. : 10/736,489
Applicants : Xia Zhao et al.
Filed : December 15, 2003
Title : Terminal Sterilization of Prefilled Containers
Group Art Unit : 1744
Examiner : Monzer R. Chorbaji
Confirmation No. : 3805
Customer No. : 32182

MAIL STOP APPEAL BRIEF – PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF TO EXAMINER'S ANSWER PURSUANT TO 37 CFR §41.41(a)

Sir:

The present paper represents a Reply Brief in response to the Examiner's Answer mailed on May 4, 2007 for the above-identified Appeal, a response to which is due by July 5, 2007. The Board is respectfully requested to consider this Reply Brief directed to three new points of argument raised in the Examiner's Answer.

I hereby certify that this correspondence is being submitted via first-class mail to MAIL STOP APPEAL BRIEF – PATENTS, United States Patent and Trademark Office on July 5, 2007.

Florence P. Trevethan
(Name of Person Submitting Paper)

Florence P. Trevethan 07/05/2007
Signature Date

I. Inherent results must necessarily flow from the applied reference.

On page 9 of the Examiner's Answer, the Examiner cites MPEP 2112 II and asserts that inherent results achieved by performing the steps of prefilling containers and then performing gamma irradiation need not be recognized by the inventors of the reference. In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flow from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The mere fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

U.S. Patent No. 6,231,936 to Kozimor indicates that the syringes disclosed therein can be filled either before or after irradiation; however, as acknowledged by the Examiner, Kozimor fails to teach that the medium of the prefilled container includes less than about 3.4 ppm of oxidizable substances after the irradiation step. See Kozimor, col. 4, lines 13-15. Although the Examiner asserts that European and/or U.S. Pharmacopoeia requirements (hereinafter the "Pharmacopoeia requirements") that include absorbance levels below 0.2 at 220-340 nm and the presence of hydrogen peroxide and other oxidizing agents to be below 3.4 ppm makes up for the deficiency of Kozimor, the inherency asserted by the Examiner is not present.

The language of claim 1 explicitly recites "prefilling the container with a medium prior to subjecting the container to a gamma irradiation sterilization treatment". Kozimor does not teach, suggest or appreciate that prefilling a syringe with the claimed medium prior to the gamma irradiation results in the benefit of maintaining oxidizable agents below a certain threshold. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. MPEP 2112 IV. Prefilling containers with a medium that includes less than about 3.4 ppm of oxidizable substances after radiation sterilization is not inherently described in Kozimor, because it is not necessarily present. Furthermore, prefilling the

container with medium to achieve the claimed invention is not and would not be recognized by persons of ordinary skill in the art. The desirability of achieving Pharmacopoeia requirements does not mean that Kozimor's method would necessarily achieve those requirements.

Therefore, because the Examiner does not provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of Kozimor, the presently claimed invention is not inherently obvious from the teachings of the prior art.

II. Following Kozimor would not necessarily result in the claimed invention.

Next, regarding paragraph 2 of the Examiner's Answer on page 10, the Examiner asserts that the result of the method in Kozimor of prefilling containers and then performing gamma irradiation need not be recognized by the inventors of the reference. Once again, Applicants cite MPEP 2112 IV, which states: To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. Even though the method in Kozimor of prefilling containers and then performing gamma irradiation need not be recognized by the inventors of the reference, the allegedly inherent characteristic must necessarily flow from the teachings of Kozimor.

Because the presently claimed invention would not necessarily flow from the teaching of Kozimor, inherency is not established. Nothing in Kozimor indicates that the claimed result (3.4 ppm oxidizable substances in the medium) would necessarily be achieved.

III. Performance of the Kozimor method would not result in the maintenance of oxidizing agents below the claimed threshold.

Finally, the Examiner asserts that the performance of Kozimor would result in the maintenance of oxidizing agents below the claimed threshold. This is not the case. Kozimor teaches that syringes can be filled either before or after irradiation, and Kozimor does not teach the presently claimed medium. The present invention is a result of a discovery of unexpected results that occur when the syringes are filled with a

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medium specifically before gamma irradiation. In particular, Example 3 of the present application demonstrates that when syringes, constructed of a radiation stable polyolefin polymer, are prefilled with a sample medium prior to the irradiation step, there is a marked improvement in sample quality when compared with syringes that were irradiated and then filled. The prior art fails to recognize the claimed method of inhibiting adverse reaction of the contents of a container subjected to a radiation sterilization procedure by prefilling the container with a medium, and therefore the performance of Kozimor would not result in the maintenance of oxidizing agents below the claimed threshold.

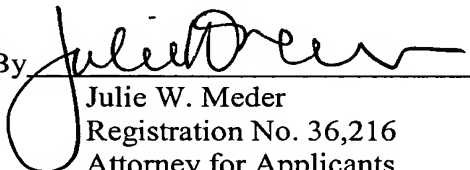
Conclusion

In view of the foregoing and the arguments presented in Appellants' Appeal Brief, the pending claims define patentable subject matter over the cited documents. Reversal of the Examiner's rejections is therefore respectfully requested.

Any questions or comments regarding this Reply Brief should be directed to the Appellants' undersigned representative.

Respectfully submitted,

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| | Art Unit | 1744 | |
| | Examiner Name | Monzer R. Chorbaji | |
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| Date | July 5, 2007 | Reg. No. | 36,216 |

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